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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,660	03/31/2005	Sierd Bron	GC715-2-PCT	2863
5100 7590 05/17/2007 GENENCOR INTERNATIONAL, INC. ATTENTION: LEGAL DEPARTMENT 925 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	
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			05/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/500,660	<b>Applicant(s)</b> BRON ET AL.	
	<b>Examiner</b> Nancy T. Vogel	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 is/are allowed.
- 6) ☒ Claim(s) 4-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/1/06, 3/29/06</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-14 are pending in the case.

Receipt of the Information Disclosure Statements on 5/1/06, and 3/29/06 is acknowledged.

### ***Sequence compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the drawings that lack sequence identifiers. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/348,080, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 60/348,080 does not disclose a purified DNA molecule comprising an inducible promoter operatively linked to the *yqjG* gene, or methods of modulating secretion of a protein of interest comprising the step of forming a second DNA molecule encoding an inducible promoter operably linked to the *yqjG* gene, or a method of modulating Sec-dependent secretion comprising providing a *Bacillus* cell comprising *spoIIIJ* and *yqjG* genes, or the *yqjG* gene, linked to an endogenous high expression promoter and modulating the expression by varying the level of induction of said promoter. This is the subject matter of claims 7-14.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Murikami (J. Bacteriol., Aprl 2002, 184, 7, 1998-2004) (cited by applicants).

Murikami et al. disclose a method of modulating Sec-dependent protein secretion comprising introducing a yqjG gene linked to an inducible promoter, which is pspac, into a Bacillus cell, and modulating the expression of the yqjG gene by varying the level of induction of the inducible promoter (see page 2000).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6, and 10-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of modulating the secretion of a protein of interest using the host cell which is Bacillus, does not reasonably provide enablement for methods for modulating the secretion of a protein of interest from other host cells. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is a method of secreting a protein of interest using any host cell transformed with DNA encoding an inducible promoter linked to the *spoIIIJ* or the *yqjG* gene, and DNA encoding the protein of interest linked to an Sec-dependent secretion signal peptide.

The state of the prior art: The prior art taught that there are striking differences between protein transport pathways in eubacteria, archaea, and eukaryotes (Pohlschaeder et al., Cell 91:563,566, 1997). Even amongst bacteria, such as *E. coli* and *B. subtilis*, there are many differences. For example, in contrast to *Escherichia coli* (See, Fekkes and Driessen, Microbiol. Mol. Biol. Rev., 63:161-173 [1999]), the Sec-dependent translocation machinery of *B. subtilis* lacks a SecB component (van Wely et al., J. Bacteriol., 181:1786-1792 [2000]). Moreover, the *B. subtilis* SecDF component, which is present as a natural fusion protein, is merely required to optimize the efficiency of protein translocation under conditions of protein hyper-secretion at gram per litre

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levels (Bolhuis et al., J. Biol. Chem., 273(33): 21217-21224, 1998), while the separate SecD and SecF proteins of E. coli are very important both for protein export and cell viability (Pogliano and Beckwith, EMBO J., 13:554-561 [1994]). In addition, in contrast to the twin-arginine translocation (Tat) machinery of E. coli that consists of the unique TatB and TatC components and the paralogous TatA and TatE components (See e.g., Robinson and Bolhuis, Nat. Rev. Mol. Cell. Biol., 2:350-356 [2001]), the Tat machinery of B. subtilis lacks distinguishable TatA/E and TatB components, while two paralogous TatC proteins with distinct functions are present (Jongbloed et al., J. Biol. Chem., 275:41350-41357 [2000];) (all cited on 1449 form).

Level of predictability in the art: There is no predictability of that any particular component of a protein transport pathway of any particular organism will function in a host cell other than that in which it originates, as shown by the many differences in secretion pathway apparatus discussed above.

Existence of working examples: The specification only discloses working examples using Bacillus as a host cell.

Breadth of claims: The claims are drawn to methods of modulating the secretion of a protein of interest using any cell type, and therefore they are very broad.

Quantity of experimentation needed: The quantity of experimentation required is extensive, since any host cell must be manipulated such that the secretion of the protein of interest can be modulated using the B. subtilis spoIIIJ and yqjG genes, which have only been shown to have and affect in B. subtilis cells.

For these reasons, it is considered that the specification does not teach how to make and use the invention commensurate with the scope of the claims.


Claims 1-3 and 13-14 are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
NANCY VOGEL  
PRIMARY EXAMINER